EPA Registration File
9402-10
Vol 1- Part 2

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager		
PRODUCT REVIEWER: STACEY Grigsby		RMB II	TEAM 34
Description of Action:		EPA File Symbol/Reg No. 9402-10	
Decision No. 356060	Submission No. 7777485	Fee for Service Action Code:	
FQPA Action Code:	Non-FQPA Action Code: 450	Fee for Service Fee:	

	MONTH	DAY	YEAR
APPLICATION DATE	APRIL	11	2005
EPA PIN DATE	APRIL	13	2005
REVIEWER ASSIGNED DATE	APRIL	14	2005
DATE DUE FROM SCIENCE			
DATE DUE TO PM	MAY	31	2005
DATE DUE OUT OF AGENCY	JUNE	03	

Type of Data:	PSB Product Chemistry ☐	PSB Acute Toxicology ☐	PSB Efficacy ☐	RASSB Environmental Fate ☐	RASSB Ecological Effects ☐	RASSB Chronic Toxicology ☐	RASSB Exposure ☐

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM.*

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

B	For Arctic Slope Contract Only	
Contractor: Arctic Slope	Contract No.: 0332	*ARCTIC SLOPE*/MANAGER
Draft Task: Signature _____ _____ (Est. hrs)	Final Task: Signature _____ _____ (Total hrs)	

C Reviewer's Comments: USE THE ATTACHED LANGUAGE

DATE FEE PAID: N/A

RESPONSE CODE: 17 RESPONSE DATE: 5/3/05

on the plastic baffle.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 3, 2005

I, Adam Heyward, Regulatory Management Branch II, Antimicrobials Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued a registration number for the product listed below to:

Kimberly -Clark Global Sales, Inc.,
2100 Winchester Road
Neenah, WI 54957

EPA Registration Number:	9402-10
Name of Product:	Kleenex Brand Anti-Viral Tissue®

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

LEWIS & HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

April 11, 2005

HAND DELIVERED

Office of Pesticide Programs
Antimicrobials Division
US Environmental Protection Agency
Crystal Mall II
1801 South Bell Street
Arlington, VA 22202

ATTENTION: **Mr. Adam Heyward**
Product Manager, Team 33

SUBJECT: **Kleenex Brand Anti-Viral Tissue (EPA Reg. No. 9402-10)**
Request for Certificate of Registration (Gold Seal)

Dear Mr. Swindell:

As agent for Kimberly-Clark Global Sales, Inc., we are requesting an original Certificate of Registration (Gold Seal) for **Kleenex Brand Anti-Viral Tissue (EPA Reg. No. 9402-10).**

Please make sure that the Gold Seal states that the "EPA has issued a registration number for the product listed below to: **Kimberly-Clark Global Sales, Inc., 2100 Winchester Road, Neenah, WI 54957.**

Please note that we are requesting an original Certificate, a copy is not sufficient for our purposes. We would greatly appreciate anything you can do to expedite the process for our obtaining this certificate

Please contact me at 202-393-3903 ext 19 when the certificate is ready so that we can arrange for a messenger to retrieve the document.

Thank you very much for your cooperation in this manner.

Sincerely,

Georgia Anastasiou

Georgia Anastasiou
Agent for,
Kimberly-Clark Global Sales, Inc.

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager	
PRODUCT REVIEWER: ADAM HEYWARD		RMB II TEAM 34
Description of Action:		EPA File Symbol/Reg No.: 9402-10
Decision No. _____	Submission No. 719575	Fee for Service Action Code: _____
FQPA Action Code: _____	Non-FQPA Action Code: _____	Fee for Service Fee: $ _____

	MONTH	DAY	YEAR
APPLICATION DATE	12	08	2004
EPA PIN DATE	12	08	2004
[redacted]IEWER ASSIGNED DATE	12	08	2004
DATE DUE TO PM			2005
DATE DUE OUT OF AGENCY			2005

Type of Data:	PSB Product Chemistry ☐	PSB Acute Toxicology ☐	PSB Efficacy ☐	RASSB Environmental Fate ☐	RASSB Ecological Effects ☐	RASSB Chronic Toxicology ☐	RASSB Exposure ☐

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM.*

No letter Required

A

DP Barcode No(s):

B	For Arctic Slope Contract Only	
Contractor: Arctic Slope	Contract No.: 0332	ARCTIC SLOPE/MANAGER
Draft Task: Signature _____ _____ (Est. hrs)	Final Task: Signature _____ _____ (Total hrs)	

C	Reviewer's Comments:

Response Code: 17	Response Date: 01-25-05

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

December 12, 2004

MEMORANDUM:

Efficacy Review EPA Reg. No. 9402-10 *Kleenex Anti-Viral Tissue*
DP Barcode 311439

From: Nancy Whyte, Efficacy Team Leader (Acting)
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

12/13/04

To: Adam Heyward, PM Team 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant:: Kimberly-Clark Corporation
2100 Winchester Road
Neenah, Wisconsin 54956

Formulation Label: **% by wt.**

Active Ingredient(s)

Citric acid	7.53%
Sodium lauryl sulfate	2.02%
Other ingredients	90.49%
Total	100.0%

I. Background:

The report of efficacy data conducted by Hill Top Research, Inc., Cincinnati, OH to determine the effectiveness of the product against Rhinovirus 2, ATCC VR-482 was received by the Product Science Branch on December 10, 2004. The testing had been done in February 2003 and was reported in MRID No. 4568754-01. Testing previously done against this organism in 2002 was not acceptable to support a label claim for effectiveness of the product

against Rhinovirus 2 because the recoverable virus titer achieved in the testing was not 10^4 for any of the three product lots tested. Efficacy data submitted at that time for four other organisms, Rhinovirus 1, ATCC VR-1364, Influenzae A, ATCC,VR-1469, Influenzae virus B, CDC !D# 2001701156 and Respiratory Syncytial Virus, ATCC VR-26 had been accepted in support of label claims. The testing was done using Good Laboratory Practices, and a Quality Assurance Statement was included in the testing report to the Agency.

II. Use Directions:

The use directions printed on the package label state that the product is to be used as a facial tissue, and has not been tested against bacteria, fungi, or other viruses. The tissues are to stored in a dry area, and disposed of promptly after use.

III. Agency Standards for Proposed Claims:

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products Test (for spray disinfectants) must be used in developing data for virucides intended for use upon dry inanimate, environmental surfaces (e.g., floors, tables, cleaned dried medical instruments). To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique with multiple replicates per dilution. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

IV. Summary of Study:

There were no specific details presented about the actual testing procedure or the preparation of the virus prior to testing. A Protocol to Measure the Virucidal Efficacy of Facial Tissues prepared by Hilltop Laboratories was included in the testing report. This document outlined the experimental design for such testing, and contained a copy of Efficacy Data Requirements for Virucides proposed by the Registration Division, Office of Pesticide Programs of the Agency in 1976 which are consistent with the requirements of DIS/TSS-7 (see above). Results of the testing were reported as follows on the next page of this review.

Inoculating Facial Tissue Disks at 15 Minute Exposure Period against Rhinovirus 2, ATCC VR-482

Log_{10} $TCID_{50}$/0.1 mL*

Test Substance	Average Titer**	Reduction in Virus Titer	Percent Reduction in Virus Titer
3-7-02-4A	0.5*	4.3	>99.99
3-7-02-4B	0.5	4.3	>99.99
3-7-02-4C 60 da. stability sample	0.5	4.3	>99.99
3-7-02-4D Control	NA	NA	NA

* Triplicate runs
NA= Not Applicable

Results of Virucidal Tests Rhinovirus 2, ATCC VR-482

Sample: 3-7-02-4A
Control: 3-7-02-4D

CYTOPATHIC EFFECT						
Dilution Inoculated	Virus Control*			Sample + Virus*		
	a	b	c	a	b	c
10^{-1}	++++	++++	++++	0000	0000	0000
10^{-2}	++++	++++	++++	0000	0000	0000
10^{-3}	++++	++++	++++	0000	0000	0000
10^{-4}	++++	++++	+00+	0000	0000	0000
10^{-5}	0++0	0+0+	000+	0000	0000	0000
10^{-6}	0000	0000	0000	0000	0000	0000
Viral Titer (Log_{10} **$TCID_{50}$/0.1 mL)	5.0	5.2	4.2	0.5	0.5	0.5
Average Viral Titer (Log_{10} **$TCID_{50}$/0.1 mL)	4.8			0.5		

*Triplicate runs
Note: + = virus recovered: 0 = no virus recovered
$TCID_{50}$ Calculated by method of Reed and Muench

Results of Virucidal Test for Rhinovirus 2, ATCC VR-482

Sample: 3-7-02-4B
Control 3-7-02-4D

CYTOPATHIC EFFECT						
Dilution Inoculated	**Virus Control***			**Sample + Virus***		
	a	**b**	**c**	**a**	**b**	**c**
10^{-1}	++++	++++	++++	0000	0000	0000
10^{-2}	++++	++++	++++	0000	0000	0000
10^{-3}	++++	++++	++++	0000	0000	0000
10^{-4}	++++	++++	+00+	0000	0000	0000
10^{-5}	0++0	0+0+	000+	0000	0000	0000
10^{-6}	0000	000+	0000	0000	0000	0000
Viral Titer (Log_{10} **$TCID_{50}$/0.1 mL)	5.0	5.2	4.2	0.5	0.5	0.5
Average Viral Titer (Log_{10} **$TCID_{50}$/0.1 mL)	4.8			0.5		

*Triplicate runs
Note: + = virus recovered: 0 = no virus recovered
$TCID_{50}$ Calculated by method of Reed and Muench

Results of Virucidal Test for Rhinovirus 2, ATCC VR-482

Sample: 3-7-02-4C (60 day Stability Study)
Control 3-7-02-4D

CYTOPATHIC EFFECT						
Dilution Inoculated	**Virus Control***			**Sample + Virus***		
	a	**b**	**c**	**a**	**b**	**c**
10^{-1}	++++	++++	++++	0000	0000	0000
10^{-2}	++++	++++	++++	0000	0000	0000
10^{-3}	++++	++++	++++	0000	0000	0000
10^{-4}	++++	++++	+00+	0000	0000	0000
10^{-5}	0++0	0+0+	000+	0000	0000	0000
10^{-6}	0000	000+	0000	0000	0000	0000
Viral Titer (Log_{10} **$TCID_{50}$/0.1 mL)	5.0	5.2	4.2	0.5	0.5	0.5
Average Viral Titer (Log_{10} **$TCID_{50}$/0.1 mL)	4.8			0.5		

*Triplicate runs $TCID_{50}$ Calculated by method of Reed and Muench
Note: + = virus recovered: 0 = no virus recovered

VI. Recommendations and Comments

1. The original viral titer was at least 10^4 (average 4.8) and efficacy testing of the product, *Antiviral Kleenex Tissue,* achieved at least a 3 $\log_{10}$ reduction in virus titer as required by DIS/TSS-7.

2. The label claim, already appearing on the product packaging, that the product is effective against Rhinovirus 2, ATCC VR-482 following 15 minutes exposure to the product, is supported by the efficacy testing submitted to the Agency.